

REMARKS/ARGUMENTS

Claim Status/Support For Claim Amendments

In response to the Office Action of April 28, 2003, Applicants request re-examination and reconsideration of this application for patent pursuant to 35 U.S.C. 132.

No new matter has been added by the amendments to the specification.

The Brief Description of the Figures was amended to add sequence identifiers for the sequences disclosed in the figures.

A protocol in the experimental section of the detailed description has been amended to properly identify the trademark SEPHAROSE using capitalization.

The abstract has been amended to remove the legal phraseology ("said").

Claim 1 has been amended. Claims 2-35 have been canceled. Claims 36-43 have been added. Claims 1 and 36-43 are pending in the instant application.

No new matter has been added by the addition of new claims 36-43. The subject matter of new claims 36-43 corresponds to the subject matter of canceled claims 3-28. The above additions to the claims also find basis in the original disclosure at page 12, lines 2-12; page 17, lines 7-14; page 18, lines 5-7 and page 27, lines 17-23. The method of claims 36-40 is described in detail at pages 20-27. Page 28, line 9 to page 29, line 5 refers to the use of

various types of samples and their measurement. Figure 1 shows data derived when using the claimed method on samples obtained from a human patient. Page 28, line 1 to page 33, line 2 describes kits and their contents contemplated for use with the claimed methods. It is clear from these specific recitations and from the description of methods utilized that the methods and types of kits were fully contemplated by the inventors at the time of filing and were enabled by virtue of the disclosure as originally filed.

Sequence Compliance

Applicants have reviewed the entire specification including the figures and the claims for sequence disclosures. The only sequence found to be disclosed is the amino acid sequence identified as SEQ ID NO:1. Applicants provided a Sequence Listing (in both paper and computer readable form) disclosing SEQ ID NO:1 on April 19, 2002. However, Applicants noted that the first and last amino acid residues of SEQ ID NO:1 (as disclosed by the sequence shown in the figures) were not included in the originally filed Sequence Listing. Applicants herein provide a diskette containing a substitute Sequence Listing in electronic computer readable form to replace the previously submitted copy (filed on April 19, 2002). The diskette submitted herewith contains a Sequence Listing which adds the first and last amino acid residues (shown in the figures) to SEQ ID NO:1. As shown in Figure 1, the

marker identified in patient sera consists of amino acid residues 2-12 of SEQ ID NO:1. When carrying out mass spectrometric procedures, it is possible to fragment a whole molecule, depending upon the enzyme used for digestion. A sequence is often predicted from these fragments but often the sequence is not identified completely. It is conventional in the art to show the missing portions of the predicted sequence in parentheses. The first (E) and last (G) amino acid residues of SEQ ID NO:1 are predicted residues as indicated by the parentheses in Figure 1. The peptide sequence without the predicted first and last amino acid residues was shown in the original specification at page 27, line 18 and is shown in the figures with the first and last predicted amino acid residues. Thus, no new matter is added, the substitute Sequence Listing is for the purpose of clarifying the use of parentheses only. Applicants also herein provide a substitute paper copy of the Sequence Listing as contained on the diskette filed herewith. The computer readable form of the substitute Sequence Listing is identical to the paper copy of the substitute Sequence Listing. The amendments to the claims and specification limiting the marker sequences to specific amino acid residues are also made for the purpose of clarification only. The claims as herein amended limit the marker sequence to amino acid residues 2-12 of SEQ ID NO:1.

Restriction/Election

The Restriction Requirement mailed on July 2, 2002 indicates that Group I included claims 1-28. In the Response of September 3, 2002, Applicants elected Group I, including claims 1-26. In the Office Action mailed on April 28, 2003, the Examiner refers to Group I as including claims 1-26. Applicants herein request the Examiner to clarify, first, if claims 27 and 28 are included within Group I and second, if claims 27 and 28 have been examined on the merits.

The instant application is related in claim format to several pending applications of which serial number 09/846,352 is exemplary. The biopolymer marker of serial number 09/846,352 was found to be novel and subsequently claims reading on methods and kits limited to its use were rejoined with the claims reading on the biopolymer marker under Ochai. In an effort to maintain equivalent scope in all of these applications, Applicants respectfully request that the Examiner reconsider the restriction requirement in the instant application to include the new claims (36-43) added herein by amendment. If the peptide consisting of amino acid residues 2-12 of SEQ ID NO:1 is found to be novel, methods and kits limited to its use should also be found novel.

Rejections under 35 USC 112 (second paragraph)

Claims 2-26, as originally presented, stand rejected under 35 U.S.C. 112, second paragraph, as being indefinite for allegedly failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The Examiner alleges that claim 2 is vague and indefinite because it is drawn to an intended use, which is not patentable. Claim 2 has been canceled, thus rendering this rejection moot.

The Examiner alleges that claims 3-5 are confusing because it is unclear what is being claimed. The Examiner states that it appears that claim 3 is a method for detecting an analyte and comparing the detected analyte to a biopolymer marker having SEQ ID NO:1; and claims 4 and 5 are methods for diagnosing a particular disease by detecting and comparing the detected biopolymer marker to SEQ ID NO:1. The Examiner further states that the recitation of "evidencing and categorizing" is confusing because it is unclear how the detected biopolymer marker is evidenced or categorized? (for example, what assay steps are involved in evidencing and categorizing?) The Examiner further states that claim 3 is vague and indefinite because it is unclear how the detected biopolymer marker evidences and categorizes a disease state.

Claims 3-5 have been canceled and the phrase "evidencing and categorizing" is not recited in any of the remaining pending claims.

The Examiner alleges that claim 3 is further confusing because it appears that after mass spectrophotometric analysis is done on a sample, the mass of the biopolymer is obtained. The Examiner states that from this, it is unclear how the mass of the biopolymer is correlated or compared to a biopolymer of SEQ ID NO:1, for example, is there a linear correlation? Or a correlation between the amino acid compositions of the detected biopolymer and those of SEQ ID NO:1? It is further confusing because if the mass of the two polypeptides is compared it is does not necessarily lead one to the same or similar sequence or even the same or similar protein. The Examiner further states that it is unclear what comprises a correlation, for example, would a 20% or 50% or 80% linear match be considered positive or negative or inclusive?

Claim 3 has been canceled. Newly added claim 36 corresponds to canceled claim 3. Claim 36 clearly recites that the mass spectrum profile of peptides elucidated from the sample is compared to the mass spectrum profile of the peptide consisting of amino acid residues 2-12 of SEQ ID NO:1. If the profile of the peptide consisting of amino acid residues 2-12 of SEQ ID NO:1 is identified within the sample profile it is concluded that the peptide consisting of amino acid residues 2-12 of SEQ ID NO:1 is found in the sample and such peptide is thus diagnostic for myocardial infarction. Furthermore, the term "correlation" (and other grammatical forms thereof) is not recited in any of the remaining

pending claims.

The Examiner alleges that claims 4 and 5 are vague and indefinite with respect to the recitation of "analytes thereof"

✓ because it is unclear what comprises analytes of a biopolymer marker.

Claims 4 and 5 have been canceled and the phrase "analytes thereof" is not recited in any of the remaining pending claims.

The Examiner alleges that claims 10-26 are vague and indefinite because it is unclear what is being claimed. The Examiner further alleges that it is unclear what comprises "analyte thereof" of the biopolymer marker having SEQ ID NO:1.

Claims 10-26 have been canceled and the phrase "analytes thereof" is not recited in any of the remaining pending claims.

The Examiner alleges that claims 15, 16, 23 and 24 are vague and indefinite because a test "sample" cannot be considered part of an assay kit. The Examiner asserts that samples are collected at the time of the assay and not pre-packaged with the reagents of a kit.

Claims 15, 16, 23 and 24 have been canceled. New added claims 41-43 are drawn to kits but do not recite test samples as components of the kits.

The Examiner alleges that claim 26 is vague and indefinite because it is drawn to an intended use, which is not patentable. Claim 26 has been canceled, thus rendering this rejection moot.

Accordingly, applicants have now clarified the metes and bounds of the claims and respectfully request that the above-discussed rejections under 35 U.S.C. 112 (second paragraph) be withdrawn.

Rejections under 35 USC 112 (first paragraph)

Claims 3-26, as originally presented, stand rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time that the application was filed, had possession of the claimed invention.

The Examiner alleges that claims 3-9 recite a method for evidencing and categorizing at least one disease state by detecting at least one biopolymer marker from a patient sample and comparing the detected biopolymer to the biopolymer marker having SEQ ID NO:1. Correlation of the detected biopolymer marker to SEQ ID NO:1 evidences and categorizes at least one disease state. The Examiner alleges that such a method is not supported by the specification as originally filed.

Claims 3-9 have been canceled. New claims 36-40 correspond with canceled claims 3-9. Claim 36 is drawn to a specific method for diagnosing myocardial infarction wherein the mass spectrometric profile of peptides elucidated from the patient sample are compared

with the mass spectrometric profile of a peptide consisting of amino acid residues 2-12 of SEQ ID NO:1. If the profile of the peptide consisting of amino acid residues 2-12 of SEQ ID NO:1 is identified within the sample profile it is concluded that the peptide consisting of amino acid residues 2-12 of SEQ ID NO:1 is found in the sample and such peptide is thus diagnostic for myocardial infarction. The term "correlation" is not recited in any of the remaining pending claims. Applicants respectfully disagree with the Examiner and assert that the method is supported by the specification as originally filed and is thus not new matter. The general objective of the method is located on page 17, lines 11-14 and the specific method is described at pages 20-27. The originally filed figures show that the peptide consisting of amino acid residues 2-12 was found in the serum of patients with a history of myocardial infarction.

The Examiner further alleges that the specification at pages 26-31 discloses how the biopolymer marker having SEQ ID NO:1 was identified from patient serum samples, however, nowhere in the specification is there a teaching of detecting any other biopolymer marker, comparing the detected marker to SEQ ID NO:1, and determining a disease state from the detected marker.

Applicants do not claim any other biopolymer markers; the claims, as pending, are drawn to a specific biopolymer marker (the peptide consisting of amino acid residues 2-12 of SEQ ID NO:1)

diagnostic for a specific disease condition (myocardial infarction).

The Examiner then requests that Applicants point out support for kits in the specification. Neither canceled claims 3-9 nor new claims 36-40 recite kits. Thus, Applicants request clarification of this section of the rejection.

The Examiner alleges that claims 10-26 recite a test kit comprising a binding partner for a biochemical marker, which includes a biopolymer marker having SEQ ID NO:1, and means for determining the binding. The Examiner alleges that such a test kit is not supported by the specification as originally filed as the specification does not contain any discussion of a test kit comprising the reagents stated above.

Claims 10-26 have been canceled. New claims 41-43 are drawn to diagnostic kits. The subject matter of a claim need not be described literally in order for the disclosure to satisfy the description requirement (see MPEP 2163.02). Claims 41-43 are drawn to a kit for determining the presence of a biopolymer marker (amino acid residues 2-12 of SEQ ID NO:1) in a sample. This objective is supported at page 18, lines 5-7. The peptide consisting of amino acid residues 2-12 of SEQ ID NO:1 diagnostic for myocardial infarction is disclosed at page 27, lines 17-23 of the instant specification and in the originally filed figures. Antibodies and reagents for assays are discussed in detail at pages 28-33 of the

instant specification.

Accordingly, Applicants have shown that they had possession of the invention, as defined by the claims as recited herein, at the time that the application was filed and thus respectfully request that this rejection now be withdrawn.

Claims 3-9, as originally presented, stand rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which allegedly was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or which with it is most nearly connected, to make and/or use the invention.

Claims 3-9 have been canceled. Claims 36-40 correspond to canceled claims 3-9. Claims 36-40 are drawn to a specific method for diagnosing a specific condition (myocardial infarction) wherein the mass spectrometric profile of peptides elucidated from the patient sample are compared with the mass spectrometric profile of a peptide consisting of amino acid residues 2-12 of SEQ ID NO:1. If the profile of the peptide consisting of amino acid residues 2-12 of SEQ ID NO:1 is identified within the sample profile it is concluded that the peptide consisting of amino acid residues 2-12 of SEQ ID NO:1 is found in the sample and such peptide is thus diagnostic for myocardial infarction. The term "correlation" is not recited in any of the remaining pending claims.

Applicants are not claiming the ability to distinguish between

disease states, nor are applicants claiming a biopolymer marker peptide of all possible diseases. Applicants are not claiming the ability to determine the incidence of disease as related to the presence or absence of a biopolymer that corresponds to the marker having SEQ ID NO:1. Applicants are not required to enable material that is not claimed (see MPEP 2164.08). The instant inventors do not attempt to develop a reference "normal", but rather strive to specify particular markers which are evidentiary of at least one particular disease state, whereby the presence of said marker serves as a positive indicator of disease (see page 5, lines 7-11 of the instant specification). The presence of amino acid residues 2-12 of SEQ ID NO:1 in bodily fluids and/or tissue samples is a positive indicator of myocardial infarction.

The Examiner asserts that the data presented in figure 1 is not convincing, nor does it clearly demonstrate that SEQ ID NO:1 is indicative of myocardial infarction (MI). According to the Examiner, a compound found in MI patients does not mean that the same compound is not present in normal or control subjects. The Examiner asserts that the specification does not provide any data for normal or control subjects.

In response to the Examiner's assertion, Applicants herein provide the attached Declaration (and Figure) under 37 CFR 1.132. The figure attached to the declaration provides side-by-side profiles (obtained using techniques of mass spectrometry) of normal

human sera versus sera from patients having a history of myocardial infarction. This profile comparison clearly evidences the absence of the 1077 dalton marker (amino acid residues 2-12 of SEQ ID NO:1) in normal human sera and thus establishes the specificity of the 1077 dalton peptide as a marker which when present in the sera is diagnostic for myocardial infarction.

In conclusion, Applicants claim that the presence of amino acid residues 2-12 of SEQ ID NO:1 is a positive indicator of myocardial infarction; a statement which is enabled by the data presented in figure 1. Applicants assert that one of ordinary skill in the art when reviewing the instant specification and declaration filed herewith would recognize how to use the claimed peptide as a marker for myocardial infarction. Thus, Applicants respectfully request that this rejection under 35 U.S.C. 112, first paragraph now be withdrawn.

Double Patenting Rejections

Claims 1-26, as originally presented, stand provisionally rejected under the judicially created doctrine of obvious-type double patenting as allegedly being unpatentable over claims 1-28 of co-pending application number 09/846,780.

The Examiner alleges that although the conflicting claims are not identical, they are not patentably distinct from each other because both applications are claiming a biopolymer marker having

a known sequence. SEQ ID NO:1 of the 09/846,780 case encompasses the SEQ ID NO:1 of the instant claims. The Examiner alleges that in addition, both applications are also claiming a method for evidencing and characterizing a disease related to the biopolymer marker having SEQ ID NO:1 and diagnostic kit for identifying the same.

The peptide of the instant application comprises amino acid residues 7-17 of the peptide of the co-pending application 09/846,780 (SEQ ID NO:1). Although the peptide of the co-pending application 09/846,780 (SEQ ID NO:1) encompasses the peptide of the instant invention and both such peptides are biopolymer markers of myocardial infarction, the instant claims have been amended herein to recite a specific peptide (amino acid residues 2-12 of SEQ ID NO:1). Claim 1 of the instant application has been amended to recite a biopolymer marker consisting of amino acid residues 2-12 of SEQ ID NO:1. Since "consisting of" is closed language and excludes any element, step or ingredient not specified in the claim (see MPEP 2111.03), the scope of the instant claims now encompass only this specific peptide (amino acid residues 2-12 of SEQ ID NO:1) thus excluding the peptide of co-pending application 09/846,780.

Accordingly, Applicants have clarified that the pending claims of the instant application are patentably distinct from the claims of co-pending application 09/846,780 and respectfully request that

this rejection now be withdrawn.

Claims 1 and 2, as originally presented, stand provisionally rejected under the judicially created doctrine of obvious-type double patenting as allegedly being unpatentable over claims 1 and 2 of co-pending application number 09/845,719.

The Examiner alleges that although the conflicting claims are not identical, they are not patentably distinct from each other because both applications are directed to the sequence ID GDFLAEAGGGVR (residues 5-15 of '719). The Examiner asserts that SEQ ID NO:1 of '719 encompasses the instantly claimed SEQ ID NO:1.

The peptide of the instant application comprises amino acid residues 6-16 of the peptide of the co-pending application 09/845,719 (SEQ ID NO:1). Although the peptide of the co-pending application 09/845,719 (SEQ ID NO:1) encompasses the peptide of the instant invention, the instant claims have been amended herein to recite a specific peptide (amino acid residues 2-12 of SEQ ID NO:1). Claim 1 of the instant application has been amended to recite a biopolymer marker consisting of amino acid residues 2-12 of SEQ ID NO:1. Since "consisting of" is closed language and excludes any element, step or ingredient not specified in the claim (see MPEP 2111.03), the scope of the instant claims now encompass only this specific peptide (amino acid residues 2-12 of SEQ ID NO:1) thus excluding the peptide of co-pending application

09/845,719. Additionally, the peptide of the instant invention is specifically diagnostic for myocardial infarction while the peptide of co-pending application 09/845,719 is diagnostic for renal failure and intracerebral hemorrhage.

Accordingly, Applicants have clarified that the pending claims of the instant application are patentably distinct from the claims of co-pending application 09/845,719 and respectfully request that this rejection now be withdrawn.

Claims 1 and 2, as originally presented, stand provisionally rejected under the judicially created doctrine of obvious-type double patenting as allegedly being unpatentable over claims 1 and 2 of co-pending application number 09/845,725.

The Examiner alleges that although the conflicting claims are not identical, they are not patentably distinct from each other because both applications are directed to the sequence ID GDFLAEAGGGVR (residues 2-12 of '725). The Examiner asserts that SEQ ID NO:1 of '725 encompasses the instantly claimed SEQ ID NO:1.

The peptide of the instant application comprises amino acid residues 3-13 of the peptide of the co-pending application 09/845,725 (SEQ ID NO:1). Although the peptide of the co-pending application 09/845,725 (SEQ ID NO:1) encompasses the peptide of the instant invention, the instant claims have been amended herein to recite a specific peptide (amino acid residues 2-12 of SEQ ID

NO:1). Claim 1 of the instant application has been amended to recite a biopolymer marker consisting of amino acid residues 2-12 of SEQ ID NO:1. Since "consisting of" is closed language and excludes any element, step or ingredient not specified in the claim (see MPEP 2111.03), the scope of the instant claims now encompass only this specific peptide (amino acid residues 2-12 of SEQ ID NO:1) thus excluding the peptide of co-pending application 09/845,725. Additionally, the peptide of the instant invention is specifically diagnostic for myocardial infarction while the peptide of co-pending application 09/845,725 is diagnostic for renal failure.

Accordingly, Applicants have clarified that the pending claims of the instant application are patentably distinct from the claims of co-pending application 09/845,725 and respectfully request that this rejection now be withdrawn.

Claims 1 and 2, as originally presented, stand provisionally rejected under the judicially created doctrine of obvious-type double patenting as allegedly being unpatentable over claims 1 and 2 of co-pending application number 09/846,780.

The Examiner alleges that although the conflicting claims are not identical, they are not patentably distinct from each other because both applications are directed to the sequence ID GDFLAEGGGV (residues 6-16 of '780). The Examiner asserts that SEQ

ID NO:1 of '780 encompasses the instantly claimed SEQ ID NO:1.

The peptide of the instant application comprises amino acid residues 7-17 of the peptide of the co-pending application 09/846,780 (SEQ ID NO:1). Although the peptide of the co-pending application 09/846,780 (SEQ ID NO:1) encompasses the peptide of the instant invention and both such peptides are biopolymer markers of myocardial infarction, the instant claims have been amended herein to recite a specific peptide (amino acid residues 2-12 of SEQ ID NO:1). Claim 1 of the instant application has been amended to recite a biopolymer marker consisting of amino acid residues 2-12 of SEQ ID NO:1. Since "consisting of" is closed language and excludes any element, step or ingredient not specified in the claim (see MPEP 2111.03), the scope of the instant claims now encompass only this specific peptide (amino acid residues 2-12 of SEQ ID NO:1) thus excluding the peptide of co-pending application 09/846,780.

Accordingly, Applicants have clarified that the pending claims of the instant application are patentably distinct from the claims of co-pending application 09/846,780 and respectfully request that this rejection now be withdrawn.

Rejections under 35 USC 102(b)

Claims 1 and 2, as originally presented, stand rejected under 35 U.S.C. 102(b) as being clearly anticipated by Nakamura et al.

(Journal of Biochemistry 94:1973-1978 1983).

The Examiner alleges that Nakamura et al. discloses the sequences of the fibrinopeptide A (from residues 1-10) that encompasses the claimed SEQ ID NO:1 (see abstract of Nakamura et al.). The Examiner asserts that even though Nakamura et al. does not teach that the peptide is indicative of a disease state, specifically MI, such an indication is seen as an intended use and is not given patentable weight.

The first sequence disclosed in the abstract by Nakamura et al. represents sixteen amino acid residues of fibrinopeptide A. SEQ ID NO:1 as disclosed in the instant application represents 13 amino acid residues of fibrinopeptide A. The 13 amino acid residue SEQ ID NO:1 of the instant invention is identical to a portion of the first sequence as disclosed by Nakamura et al.

Claim 1 has been amended and claim 2 has been canceled. Claim 1 encompasses the subject matter of canceled claim 2. Claim 1 has been amended to recite a biopolymer marker consisting of amino acid residues 2-12 of SEQ ID NO:1. Since "consisting of" is closed language and excludes any element, step or ingredient not specified in the claim (see MPEP 2111.03), the scope of the instant claims now encompass only this specific peptide (amino acid residues 2-12 of SEQ ID NO:1) and thus excludes the peptides disclosed by Nakamura et al. Claim 1 identifies a specific peptide (amino acid residues 2-12 of SEQ ID NO:1) with a specific function (diagnostic

for myocardial infarction (MI)). Claim 1 now recites a specific use for the claimed biopolymer marker. Nakamura et al. do not teach that their first sequence or any portion thereof is diagnostic for myocardial infarction (MI).

Accordingly, Applicants respectfully submit that the claim, as instantly presented, now distinguishes over the compositions taught by Nakamura et al. and respectfully request that this rejection be withdrawn.

Claims 1, 2 and 10-26, as originally presented, stand rejected under 35 U.S.C. 102(b) as being clearly anticipated by Grieninger et al. (US 5,817,768).

The Examiner asserts that Grieninger et al. discloses fibrinogen protein as well as monospecific antibodies to different individual epitopes of the alpha subunit of fibrinogen. Grieninger et al. teaches antibodies conjugated to detectable labels and solid substrate materials for use in convention assays to detect fibriongen (see columns 4 and 5 of Grieninger et al.). The Examiner asserts that Grieninger et al. also teaches kits comprising anti-fibrinogen antibodies, means for detecting the binding in the form of labeled markers and substrate surfaces (see column 6, lines 17-26 of Grieninger et al.).

Claim 1 has been amended and claims 2 and 10-26 have been canceled. Claim 1 encompasses the subject matter of canceled claim

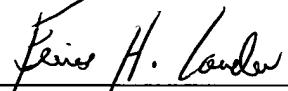
2. New claims 41-43 are drawn to kits. Claim 1 has been amended to recite a biopolymer marker consisting of amino acid residues 2-12 of SEQ ID NO:1. Since "consisting of" is closed language and excludes any element, step or ingredient not specified in the claim (see MPEP 2111.03), the scope of the instant claims now encompass only this specific peptide (amino acid residues 2-12 of SEQ ID NO:1) and thus excludes the peptides disclosed by Grieninger et al. Claim 1 identifies a specific peptide (amino acid residues 2-12 of SEQ ID NO:1) with a specific function (diagnostic for myocardial infarction (MI)). The kits of new claims 41-43 utilize this specific peptide (amino acid residues 2-12 of SEQ ID NO:1) and are diagnostic for a specific condition, myocardial infarction. Grieninger et al. does not teach the specific peptide (amino acid residues 2-12 of SEQ ID NO:1) nor does Grieninger et al. teach that such specific peptide or any portion of fibrinogen is diagnostic for myocardial infarction.

Accordingly, Applicants respectfully submit that the claims, as instantly presented, now distinguish over the compositions taught by Grieninger et al. and respectfully request that this rejection be withdrawn.

CONCLUSION

In light of the foregoing remarks, amendments to the specification and amendments to the claims, it is respectfully submitted that the Examiner will now find the claims of the application allowable. Favorable reconsideration of the application is courteously requested.

Respectfully submitted,



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